YOUNG-HEALTH INDUSTRIAL CO., LTD.

No. 7, NANKANN SHIAH, LU-CHU SHIANG, TAOYUAN HSIEN, TAIWAN, ROC 338
Telephone: 886-3-3250866 Fax: 886-3-3250870
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JUN 1 3 2001

510(K) SUMMARY K002727

Submitter's Name:	YOUNG-HEALTH INDUSTRIAL CO., LTD.
Address:	No.7, NANKANN SHIAH, LU-CHU SHIANG, TAOYUAN HSIEN 338, TAIWAN, ROC
Phone:	886-3-3250866
Contact:	Yang, Rong-Jeh
Date of Summary:	August 27, 2000
Name of Device:	YOUNG-HEALTH SUPER EAR THERMOMETER YA-901
Predicate Device:	1. TEMP TELLER - INFRARED TYMPANIC THERMOMETER TT-201 (K984497); 2. BRAUN THERMOSCAN IRT 3020/3520 THERMOMETER (K983295).
Device Description:	The YOUNG-HEALTH SUPER EAR THERMOMETER YA-901 is a hand held instrument that measures temperature through the opening of the auditory canal. Operation is based on measuring the natural thermal radiation emitted from the tympanic membrane and adjacent surfaces.
Intended Use:	The device is an electronic clinical thermometer using an infrared thermopile sensor to detect body temperature of the radiation from the tympanic part of the human of all ages. It is intended for use on people of all ages in the home.

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Technological Characteristics:

The YOUNG HEALTH SUPER EAR THERMOMETER Model YA-901 has the same sensor technology as the BRAUN THERMOMETER Model IRT 3020/3520 (K983295). The YOUNG HEALTH SUPER EAR THERMOMETER Model YA-901 and the BRAUN THERMOMETER Model IRT 3020/3520 have the same primary function of measuring body temperature.

The YOUNG HEALTH SUPER EAR THERMOMETER YA-901, TEMP TELLER TT-201, and the Braun Thermoscan IRT 3020/3520 have the same intended use, general design and incorporate similar materials and components.

The YOUNG HEALTH SUPER EAR THERMOMETER hence raises no new questions of safety and effectiveness.

YOUNG HEALTH concludes that the Super Ear Thermometer YA-901 is substantially equivalent to the TEMP TELLER Infrared Tympanic Thermometer TT-201 and BRAUN THERMOMETER Model IRT 3020/3520

PRODUCT SPECIFICATIONS

COMPONENTS:	There are five parts composing the device, i.e., Protect Envelop, Protect Cover, Upper Cover, Bottom Cover, and PC Board. The part, which will contact the patient tissue, is the Protect Envelop (probe cover). This Protect Envelop is a disposable component and the other four parts are the reusable components.
SENSOR:	Heimann TPS434 Thermopile Sensor
SIGNAL PROCESSING & DISPLAY:	Signal processing -- TD-02 Microchip & Burr-Brown OPA2366 Operational Amplifier Display -- 4 x 16 segments LCD display

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POWER REQUIREMENTS:	DC 3V, two #4 AAA 1.5V cells
MATERIALS:	Main structure material of the body – ABS (D-150) Material of the (Protect Envelop) probe cover – PAXOTHENE, low density polyethylene resins, NA112-27, meets FDA food packaging applications regulations established in 21 CFR 177.1520.

OPERATIONAL SPECIFICATIONS:

Measuring Temperature Range:	32 ℃ - 43 ℃ (89.6 ^{0}F – 109.4 ^{0}F)
Operating Temperatures:	20 ℃ - 30 ℃ (68 ^{0}F – 86 ^{0}F)
Storage Environment:	10 ℃ - 40 ℃ (50 ^{0}F - 104 ^{0}F), 30 ~ 95 % R.H.
Resolution & repeatability:	0.1℃ or 0.1 ^{0}F
Accuracy	
Less Than 36 ℃ (96.8 ^{0}F)	± 0.3 ℃ (0.5 ^{0}F)
36.0 ℃~39.0 ℃ (96.8 ^{0}f ~102.2^{0}f)	± 0.2 ℃ (0.3 ^{0}F)
Above 39.0 ℃	± 0.3 ℃ (0.5 ^{0}F)
Steady-State Reading Time:	1 second operation
Electric Power:	DC 3V (two #4 AAA 1.5V cells)
Night Operation:	Cool back-light function
Temperature Units:	Dual units, Celsius or Fahrenheit
Power-Save Function:	Auto turn-off after 60-second sleep action

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Alarm Function:	Low battery indicator
Complete Operation Inform:	Beep sound
Electric Insulation:	Type BF applied part
Indication Screen:	Large LCD screen display
Algorithms:	The device is designed to scan the body temperature continuously, and shows directly the measured highest temperature on the screen. The operator is informed to consider the differences of temperature between the tympanic and other sites.
Other Capabilities:	Temperature history – Automatic record of last ten temperature data.

BIOLOGICAL SPECIFICATIONS:

Patient tissue and fluid contacting component is Protect Envelop (probe cover). Its material is PAXOTHENE, low-density polyethylene resins, which meet US FDA regulations for food packaging applications, established in code of Federal Regulation, 21 CFR, Section 177.1520. They do not contain any ODS, ozone delete substance. They are safe and hygienic.

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SUMMARY OF TESTING:

Non-Clinical Results

Performance Test	Results
Environment Accuracy Test	PASS
Cleaning Test	PASS
Acoustic Noise Test	PASS
Electromagnetic Compatibility	PASS

Product performance specifications, features and software were validated

Clinical Results

A clinical study demonstrated that the YOUNG-HEALTH SUPER EAR THERMOMETER YA-901 measures the ear temperature data that are correlated to those measured by standard electronic clinical temperature at oral part. The correlation result is similar to that of Chou et al.*

* Chou YH, et al. Clinical evaluation of a new thermometer: infrared tympanic thermometer. The 125th annual meeting of Chinese Taipei Pediatric Association, 1990.

Conclusion

Based on the above comparison information, the YOUNG HEALTH SUPER EAR THERMOMETER YA-901 raises no new questions of safety or effectiveness.

YOUNG HEALTH concludes that the Super Ear Thermometer YA-901 is substantially equivalent to the TEMP TELLER Infrared Tympanic Thermometer TT-201 and BRAUN THERMOMETER Model IRT 3020/3520

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2001

Mr. Yang Ronk-Jeh
President
Young Health Industrial Co., LTD.
No.7 Nankann Shiah,
Lu-Chu Shiang
Taoyuan Hsien
TAIWAN, ROC

Re: K002727
Trade/Device Name: Young-Health Super Ear Thermometer
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: March 27, 2001
Received: March 30, 2001

Dear Mr. Ronk-Jeh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510 (K) NUMBER (IF KNOW): K002727

DEVICE NAME: YOUNG-HEALTH SUPER EAR THERMOMETER YA-901

INDICATIONS FOR USE:

The device is an electronic clinical thermometer using an infrared thermopile sensor to detect body temperature of the radiation from the tympanic part of the human of all ages. It is intended for use on people of all ages in the home.

Patricia Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002727

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use _____ OR Over—The—Counter—Use X

(Per 21 CFR 801.109) (Optional Format 1-2-96)